

Appl. No. : 09/931,399
Filed : 08/16/2001



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

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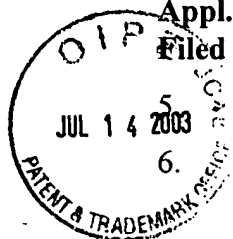
Applicant : Betageri, Guru)
Appl. No. : 09/931,399)
Filed : 08/16/2001)
For : ENTERIC-COATED)
PROLIPOSOMAL)
FORMULATIONS FOR)
POORLY WATER SOLUBLE)
DRUGS)
Examiner : Kishore, G.)

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Guru Betageri, Ph.D., do hereby declare as follows:

1. I am Professor and Chairman of the Department of Pharmaceutical Sciences, College of Pharmacy, Western University of Health Sciences in Pomona, CA 91766. I have personal knowledge of the matters set forth herein, and if called upon to testify, I could and would testify competently thereto.
2. I am the sole inventor in the above-captioned case.
3. I prepared pharmaceutical formulations using both the method described in the above-captioned application at Example 2 ("Betageri") and the method disclosed in U.S. Pat. No. 4,615,885 to Nakagame at Example 1 ("Nakagame") to generate a comparison of the products produced by the two methods. For both methods, DMPC was used as the phospholipid. DMPC is a synthetic phospholipid. Nakagame explicitly indicates that a synthetic phospholipid can be used in accordance with his invention (Col. 2, lines 46-48).
4. I tested the following five drugs using both methods: nicotinamide, benzocaine, hydrochlorothiazide, aspirin, and erythromycin.



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I quantitatively and qualitatively analyzed the products produced by both methods.

6. The following tables represent true and correct summaries of my results:

Table 1: Quantitative Analysis Based On Percent Yield

Pharmaceutical	Percent Yield Betageri	Percent Yield Nakagame	Increase in Yield
Nicotinamide	94%	56%	68%
Benzocaine	95%	44%	116%
Hydrochlorothiazide	95%	98%	-
Aspirin	96%	69%	39%
Erythromycin	96%	56%	71%
<i>Average</i>	95%	65%	74%

Table 2: Quantitative Analysis Based On Concentration

Pharmaceutical	Concentration (ug/ml) Betageri	Concentration (ug/ml) Nakagame	Increase in Concentration
Nicotinamide	5.629	3.557	58%
Benzocaine	22.560	11.571	95%
Hydrochlorothiazide	23.707	8.622	175%
Aspirin	6.898	3.692	89%
Erythromycin	584.193	506.863	15%
<i>Average</i>			86%

Table 3: Qualitative Analysis

Pharmaceutical	Color of Final Product Betageri	Color of Final Product Nakagame
Nicotinamide	White Powder	Yellow Powder (Degradation)
Benzocaine	White Powder	Orange/Pink Flakes (Degradation)
Hydrochlorothiazide	White Powder	White Flakes
Aspirin	White Powder	White Flakes
Erthromycin	White Powder	Orange Brown (Degradation)

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I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Executed on July 9, 2003, at Pomona, California.

By: 
Dr. Guru Betageri